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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :

Inventors George Kindness : Group Art Unit: 1614
Brooke Schumm III :
F. Timothy Guilford :

Appl. No. 09/997,490 : Examiner: unnamed

Filed: November 17, 2001 :

For: A COMBINATION AND METHOD OF TREATMENT OF CANCER
UTILIZING A COX-2 INHIBITOR AND A 3-HYDROXY-3-METHYLGLUTARYL-
COENZYME-A (HMG-CoA) REDUCTASE INHIBITOR

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner
of Patents and Trademarks
Washington, D.C. 20231

Sir or Ma'am:

Enclosed are four items for the Information Disclosure Statement in this case. They are separated by blue pages

Item 1) After being renumbered for this case, a copy of first Information Disclosure Statement filed on July 25, 2001, in Kindness et al, Serial No. 09/912,703, (filed July 25, 2001). Copies of all items available in S/N 912,703 file and available on request.

Item 2) After being renumbered for this case, a copy of Supplemental Information Disclosure Statement filed on October 1, 2002 in Kindness et al, Serial No. 09/912,703, (filed July 25, 2001). Copies of all items available in S/N 912,703 file and available on request.

Item 3) Copy of International Search Report issued in Kindness et al, PCT/US01/31328, filed October 6, 2001 with enclosures.

Item 4) A 2nd Information Disclosure Statement that may be pertinent to examination with articles attached as indicated.

Respectfully submitted,

Brooke Schumm III
Pat. Atty. #34,926

Daneker, McIntire, Schumm, Prince
Goldstein, Manning & Widmann, P.C.
210 N. Charles St.
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on behalf of Applicants

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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/997,490
		Filing Date	17 nov 2001
		First Named Inventor	KINDNESS
		Art Unit	1614
		Examiner Name	
Sheet 1 of 2	Attorney Docket Number		

U.S. PATENT DOCUMENTS					
Examiner Initials ⁵	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 5,747,459	05-05-1998	Rowe	general (not attached)
		US-			
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FOREIGN PATENT DOCUMENTS						
Examiner Initials ⁵	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passage or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 01/45698 A1	06-28-2001	Merck	cover and pp. 1-2 attached	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449B/PTO

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	09/997,490
Filing Date	17 Nov 2001
First Named Inventor	KINDNESS
Group Art Unit	1614
Examiner Name	
Attorney Docket Number	

Examiner Initials	Cita No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T2
		<p>Please see attached 2 sheets of references with enclosures except as indicated.</p>	

**Examiner
Signature**

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT**

Sheet 1 of 2

Appl. No. 09/997,490

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First Named Inventor: Kindness

Group Art Unit: 1614

Examiner Name:

Atty. Docket No.

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Author in CAPITAL LETTERS, title of article, title of item, date, page, vol-issue, publisher, city and /or country where published	T
		SHIRAMA, T, Relation between Cyclooxygenase-2 Expression and Tumor Invasiveness and Patient Survival in Transitional Cell Carcinoma of the Urinary Bladder, CANCER vol. 92 (1): 188193 (July 1, 2001) (Amer. Cancer Socy. 2001)	
		EVANGELOU, A, Is There any Role for Antioxidants in Cancer Prevention and Treatment, Abstract No. 85, IAR Conference on Antioxidants in Cancer Prevention and Therapy, June 4-7, 2001, Anticancer Research 21(3A): 1565 (May-June 2001).	
		GALARIS, D, Biological Antioxidants, Abstract No. 86, IAR Conference on Antioxidants in Cancer Prevention and Therapy, June 4-7, 2001, Anticancer Research 21(3A): 1565 (May-June 2001).	
		DOVAS A, The Role of Free Radicals and Metal Ions in the Generation and Prevention of Oxidative Disease, Abstract No. 84, IAR Conference on Antioxidants in Cancer Prevention and Therapy, June 4-7, 2001, Anticancer Research 21(3A): 1564-65 (May-June 2001).	
		ROBERTSON, F M et al, Cyclooxygenase as a Therapeutic Target in Breast Cancer, Abstract No. 176, IAR Conference on Antioxidants in Cancer Prevention and Therapy, June 4-7, 2001, Anticancer Research 21(3A): 1611 (May-June 2001).	
		CLEMENT IP et al, Methylselenocysteine Modulates Proliferation and Apoptosis Biomarkers in Premalignant Lesions of the Rat Mammary Gland, Anticancer Research 21: 863-868(2001).	
		RATNASINGHE D et al, Cyclooxygenase-2, P-glycoprotein-170 and Drug Resistance; Is Chemoprevention Against Multidrug Resistance Possible, Anticancer Research 21:2141-2148 (2001).	
		HSU, A et al, The Cyclooxygenase-2 Inhibitor Celecoxib Induces Apoptosis by Blocking Akt Activation in Human Prostate Cancer Cells Independently of Bcl-2, J. Biol. Chem. 275(15): 11397-11403, April 14, 2000 (Amer. Socy. For Biochemistry and Molecular Biology, Inc. 2000)	
		TALLEY J et al, 4-[5-Methyl-3-phenylisoxazol-4-yl]-benzenesulfonamide, valdecoxib: a potent and selective inhibitor of COX-2, J. Medicinal Chemistry, 43(5): 775-777 (Mar. 9, 2000) (no text attached)	

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STATEMENT BY APPLICANT**

Sheet 2 of 2

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		TALLEY J et al, N-[[5-methyl-3-phenylisoxazol-4-yl]phenyl]sulfonyl]propanzamide, sodium salt, parecoxib sodium: A potent and selective inhibitor of COX-2 for parenteral administration, J. Medicinal Chemistry, 43(9): 1661-1663 (May 4, 2000) (no text attached)	
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